The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GUST H. BARDY and GEORGE KLEIN

MAILED

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PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 2003-1338
Application No. 09/441,936

ON BRIEF

Before COHEN, ABRAMS, and FRANKFORT, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-5, 10, 13, 14, 17, 18 and 23. Claims 6-9, 11, 12, 15, 16 and 19-22 have been allowed.

We REVERSE AND REMAND TO THE EXAMINER.

BACKGROUND

The appellants' invention relates to an external atrial defibrillator. An understanding of the invention can be derived from a reading of exemplary claim 1, which has been reproduced below.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Morgan et al. (Morgan)	4,610,254	Sep. 9, 1986
Adams et al. (Adams '219)	5,207,219	May 4, 1993
Adams et al. (Adams '925)	5,509,925	Apr. 23, 1996
Ferrari	5,824,033	Oct. 20, 1998
Brandell	6,068,651	May 30, 2000 (filed Mar. 26, 1998)
Skelton et al. (Skelton)	6,292,692	Sep. 18, 2001 (filed Apr. 30, 1999)

The following rejections stand under 35 U.S.C. § 103(a):

(1) Claims 1, 2, 10, 13 and 18 on the basis of Adams '219 in view of Morgan.

(2) Claim 3 on the basis of Adams '219 in view of Brandell.

(3) Claim 4 on the basis of Adams '219 in view of Skelton.

(4) Claims 5 and 14 on the basis of Adams '219 in view of Morgan and Ferrari.

(5) Claim 17 on the basis of Adams '925 in view of Adams '219.

(6) Claim 23 on the basis of Adams '219.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 11) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 10) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

Representative Claim 1

An atrial defibrillator, comprising:

a portable, non-implantable housing;

a pair of defibrillator pads operable to be applied to the outside of a patient's body;

a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads in response to a shock command from an operator;[1] and

an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is

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[1]It is clear from the disclosure of the invention in the specification that the term "operator" is to be interpreted to mean the patient or another human being, rather than an automatic device that causes the shock generator to operate. In this regard note, in particular, the explanation on page 3 that this allows the patient to choose when to receive a shock, rather than having the shock automatically imposed as is the case with automatic implanted defibrillators.

experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial defibrillation.

Rejection (1)

The examiner has rejected claims 1, 2, 10, 13 and 18 as being obvious[2] in view of the combined teachings of Adams '219 and Morgan. With regard to independent claim 1, the examiner has found that all of the subject matter recited in the claim is disclosed or taught by Adams '219 except for the shock generator being operable in response to a shock command from an operator. In arriving at this finding, the examiner has taken the view that while Adams '219 is directed to a non-portable implantable defibrillator, the mention in the background section of the reference that atrial defibrillation also has been performed by portable non-implantable defibrillators is sufficient to suggest to one of ordinary skill in the art that the Adams '219 invention also could be applied to portable non-implantable defibrillators, from which we presume that the examiner is of the opinion that the Adams '219 defibrillator could be so modified.

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[2]The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

As for the shock generator being operable in response to a command from an operator, the examiner has concluded it would have been obvious to further modify the Adams '219 defibrillator to provide this feature for the shock generator. The thrust of the appellants' arguments in rebuttal is that modifying the Adams '219 defibrillator in the manner proposed by the examiner would not have been obvious to the artisan, for to do so would destroy the patented invention by virtue of requiring a total reconstruction thereof from an automatic implantable defibrillator to a manually operated portable external defibrillator, suggestion for which is found only in the hindsight afforded one who first viewed the appellants' disclosure. For the reasons expressed below, we find ourselves in agreement with the appellants.

Adams '219 is directed to

> a fully automatic implantable atrial defibrillator which exhibits improved safety by reducing the potential risk of induced ventricular fibrillation which may result from the mistimed delivery of cardioverting electrical energy to the atria of the heart (column 1, lines 11-15).

While this reference comments that atrial fibrillation can be corrected by way of portable external defibrillators (column 1, lines 29-31), the disclosed invention has as its objective overcoming the risk of mistimed delivery of cardioverting energy by making the device implantable and fully automatic, so that the patient does not have to activate the defibrillator on his/her own (column 1, line 48 et seq.). To accomplish this, the invention provides an implantable atrial defibrillator that includes first detecting means

for detecting ventricular activations of the heart, second detecting means for detecting atrial activity of the heart, and means for determining when the atria are in need of cardioversion (defibrillation) and for cardioverting the atria upon such determination (column 3, lines 26-40). As explained in columns 6 and 7, when the device determines that atrial cardioversion is necessary, it will "immediately discharge the electrical energy stored in the capacitor . . . to the atria" (column 7, line 61 et seq.).

From our perspective, one of ordinary skill in the art would have understood from Adams '219 that the invention requires an implantable atrial defibrillator that functions automatically without the need for action by an operator. Thus, we cannot agree with the examiner's conclusion that the mere mention in this reference of external atrial defibrillators activated by an operator would have made it obvious to one of ordinary skill in the art to modify the Adams '219 invention by converting it from an implanted fully automatic device to an external manually operated device. To do so would defeat the objectives of the Adams '219 invention and necessitate a wholesale reconstruction of the device and its operation, which in our view would function as a disincentive to the artisan to make the modification.

Morgan is directed to a device for defibrillating the ventricles of the heart, and has as an objective presenting the data obtained from the analyzer and then obtaining the assent of the operator, whether it be the patient or another, to administer the electrical shock by manual activation of the device. Continuing along the line of

reasoning expressed in the preceding paragraph, it is our further view that it would not have been obvious to one of ordinary skill in the art to modify the Adams '219 defibrillator by making the shock generator operate in response to the input of an operator rather than automatically, for to do so would subvert the major stated objective of that invention.

It therefore is our conclusion that the combined teachings of Adams '219 and Morgan fail to establish a prima facie case of obviousness with regard to the subject matter recited in independent claim 1, and we will not sustain this rejection. It follows that we also will not sustain the like rejection of claims 2 and 10, which depend from claim 1.

Independent method claim 13 requires the steps of receiving a cardiac signal from a patient, determining from the signal whether the patient is experiencing atrial fibrillation, receiving a shock command from an operator, and shocking the patient with a portable shock generator in response to the shock command if the patient is experiencing atrial fibrillation. This claim also stands rejected as being unpatentable over Adams '219 in view of Morgan. As was the case with claim 1, it is our view that to modify the Adams '219 defibrillator in such a manner as to perform the steps of claim 13 would be contrary to the manner in which it is intended to function, and would necessitate that substantially all of its features be modified or discarded. Therefore, on

the basis of the same reasoning as we applied to the rejection of claim 1, we also will not sustain the rejection of independent claim 13 and dependent claim 18.

Rejection (2)

Independent claim 3 has been rejected as being unpatentable over Adams '219 in view of Brandell. This claim recites a portable, non-implantable housing. It includes an analyzer in the housing and operable to receive a cardiac signal from the patient, to determine whether the patient is experiencing atrial fibrillation, and to enable a shock generator if the patient is experiencing atrial fibrillation. The claim further requires that there be a safety device disposed in the housing "operable to prevent the patient from activating the shock generator." It is the examiner's position that Adams '219 discloses or teaches all of the subject matter recited in this claim except for the safety device, the addition of which to Adams '219 the examiner believes would have been obvious in view of Brandell.

As we determined above with regard to claim 1, it would not have been obvious to one of ordinary skill in the art to modify Adams '219 to the extent that it is converted from an automatic implanted atrial defibrillator to a manually operated portable defibrillator, and this rejection also fails at that point. As far as Brandell is concerned, we further are of the view that it would not have been obvious to add the required safety device to the Adams '219 defibrillator, for this would necessitate replacing the

automatic operation with a manual override, thus destroying a key objective of the Adams '219 invention.

A prima facie case of obviousness is not established by Adams '219 and Brandell, and the rejection of claim 3 cannot be sustained.

Rejection (3)

The examiner here rejects independent claim 4 as being obvious in view of Adams '219 and Skelton, the latter being cited for teaching a verification device for preventing the defibrillator from being operated by an unauthorized person. Claim 4 contains the same limitations regarding the defibrillator being portable and non-implantable and an analyzer that enables the shock generator if the patient is experiencing atrial fibrillation. In addition, it recites a verification device disposed in the housing and "operable to prevent an unauthorized person from activating the shock generator."

We will not sustain this rejection for the same reasons as those set forth above with the other independent claims. That is, to modify the Adams '219 defibrillator in the manner proposed by the examiner, in particular, so that the shock generator is activated by an operator rather than automatically, would destroy the invention to which the patent is directed, and therefore would not have been obvious to one of ordinary skill in the art. This problem is not overcome by further consideration of the teachings of Skelton.

Rejection (4)

The rejection of claims 5 and 14 on the basis of Adams '219, Morgan and Ferrari also cannot be sustained. Claim 5 adds to apparatus claim 1 the requirement that the analyzer receives the cardiac signal from the pair of defibrillator pads, and claim 14 adds to method claim 13 the steps of applying the defibrillator pads to the patient, receiving cardiac signals via the pads, and shocking the patient via the pads.

Ferrari has been applied to the basic combination of Adams '219 and Morgan for its teaching of utilizing electrode pads that are capable of both receiving a cardiac signal and applying a defibrillation pulse. However, Ferrari does not cure the deficiencies discussed above in establishing a prima facie case of obviousness with regard to the subject matter in claims 1 and 13 with the combined teachings of Adams '219 and Morgan. This being the case, the rejection of claims 5 and 14 cannot be sustained.

Rejection (5)

Claim 17 stands rejected as being unpatentable over Adams '925 in view of Adams '219. It is the examiner's position that Adams '925 discloses all of the subject matter in method claim 17 except for the requirement that the defibrillator be portable. However, as before, it is the examiner's view that the use of portable defibrillators to counteract atrial fibrillation is acknowledged in Adams '219, and therefore it would have been obvious to one of ordinary skill in the art to modify the Adams '925 system by

utilizing a portable defibrillator rather than the implanted defibrillator disclosed in the reference. We do not agree, essentially on the basis of the arguments we set out above in our discussion of the same issue with regard to claim 1. Like Adams '219, Adams '925 discloses an implantable defibrillator that operates automatically to apply a shock to the patient at the appropriate time. To modify Adams '925 such that it becomes a portable unit would defeat the objectives of the invention, as well as necessitating a total reconstruction thereof and thus, as was the case with claim 1, these factors would operate as a disincentive to make the proposed modification.

The references thus fail to establish a prima facie case of obviousness with regard to the subject matter of claim 17, and we will not sustain the rejection.

Rejection (6)

Claim 23 stands rejected as being unpatentable over Adams '219. This claim recites, inter alia, a portable, non-implantable housing, pads, and a shock generator operable to shock a patient via the pads with a multi-phasic waveform. The examiner's positions with regard to claim 23 are (1) it would have been obvious to convert the disclosed automatic implanted defibrillator to a portable non-implantable one because the reference teaches that portable defibrillators also have been used for atrial defibrillation, and (2) the use in the Adams '219 defibrillator of the claimed waveform would have been an obvious matter of design choice since such "is a matter of treatment optimization" (Answer, page 9).

For the reasons stated above in our discussions of the various rejections based upon Adams '219, we do not agree that suggestion exists for modifying the disclosed defibrillator in accordance with the examiner's proposal. Adams '219 does not disclose or teach using a multi-phasic waveform in atrial defibrillation, and there is no evidence to support the examiner's contention that such a waveform was known in the art for atrial defibrillation at the time of the appellants' invention, much less that it would have been an obvious matter of design choice to do so in the Adams '219 system.

For the foregoing reasons, we will not sustain the rejection of claim 23.

Remand To The Examiner

The appellants have admitted in their specification that it was known to shock a patient who is experiencing atrial fibrillation by means of portable external defibrillators (page 2, lines 8-14) as well as implanted defibrillators (page 2, lines 24-29). It would appear from the discussion of these devices that the shock generators in both can be discharged manually by an operator at an appropriate time. The use of external atrial defibrillators is confirmed in Adams '219 (column 1, lines 28-31), and this reference also discloses a system wherein the presence of atrial fibrillation is determined and the shock generator is enabled and then automatically discharged by the device.

All of the claims under rejection in this case require that the defibrillator be "portable" and/or "non-implantable," yet three of the four of the applied references are directed to implantable defibrillators, and only the fourth, which was applied for

teaching multi-use pads, discloses a portable machine. Since some means must be present for indicating the presence of atrial defibrillation in a patient in order to determine whether and when a shock is appropriate in the use of portable defibrillators, it would seem that the field of portable defibrillators would be fertile ground for a search of the applicable prior art in the process of evaluating the patentability of the appellants' claims. In this regard, claim 1 requires only a portable housing, a pair of pads, a shock generator, and an analyzer to indicate the presence of atrial fibrillation in such a manner as to allow an operator to manually cause the shock generator to discharge. Claim 13 requires only the steps of receiving a cardiac signal from the patient, "determining" whether atrial fibrillation is present, receiving a shock command from an operator, and then shocking the patient. Claim 17 contains basically the same steps, plus "determining" the patient's heart rate and that the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range. In claims 13 and 17, it would appear that the language is broad enough to cover "determining" by other than automatic means.

This application therefore is remanded to the examiner for consideration of further action pursuant to the comments set forth in the two paragraphs immediately above.

CONCLUSION

None of the rejections is sustained.

The decision of the examiner is reversed.

This application is remanded to the examiner for action commensurate with the comments made above by this panel of the Board.

REVERSED AND REMANDED

IRWIN CHARLES COHEN
Administrative Patent Judge

NEAL E. ABRAMS
Administrative Patent Judge

CHARLES E. FRANKFORT
Administrative Patent Judge

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